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ACCESS TO LIFE-SAVING MEDICINES: REAL CHANGE IN THE PERU FTA

The pharmaceutical provisions of the Peru FTA provide "proof that a balance between fostering drug innovation and ensuring access to affordable medicines can be achieved."

The Peru FTA is "the first bilateral U.S. trade agreement endorsed by the Generic Pharmaceutical Association."

– *Generic Pharmaceutical Association, May 31, 2007*

"The new Peru provisions represent a decisive step away from the policy of leveraging trade deals to obstruct access to medicines...the new rules are a victory for advocates and policymakers worldwide."

– *The Center for Policy Analysis on Trade and Health, July 5, 2007*

An "important [step] toward making trade work for poor people and developing countries...We particularly welcome the significant achievement made in reducing the onerous requirements for intellectual property protections for pharmaceuticals...This will make a real difference in preserving access to affordable medicines."

– *OXFAM, Letter to Speaker Pelosi, May 31, 2007*

Dear Colleague:

The May 10 Agreement achieved by House Democrats made major breakthroughs in U.S. trade policy. One core feature of the new policy is a greatly improved chapter on intellectual property, which will serve to improve access to affordable medicines in Peru, and assist that country in meeting public health challenges. These improvements have been commended even by groups like OXFAM that do not support the Peru free trade agreement generally.

There are four key provisions in the amended Peru FTA that will improve access to medicines. These provisions:

(1) **Limit Patent Term Extensions Due to Delays in Patent Issuance or the Marketing Approval Process:** Previous FTAs provided for mandatory extensions – beyond the 20 year patent term – for pharmaceutical patents when there were delays in the patent issuance or marketing approval process. This greatly delayed access to affordable medicines for the patient. The new text developed by House Democrats eliminates such extensions and, to minimize the impact on innovative pharmaceutical companies, requires Peru to process applications expeditiously, with assistance and cooperation from the United States.

(2) **Permit "Concurrent" Data Exclusivity Periods in the United States and Peru:** Under the original provision, a generic manufacturer would have to wait "at least"

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five years before it could get approval to sell its product in Peru using the clinical test data of an innovative drug manufacturer. The five-year clock would not start until the innovative drug manufacturer entered the Peruvian market, in some cases many years after the drug was available in the United States. House Democrats created important exceptions to allow the clock to start running in Peru much earlier – at the same time the drug is made available in the United States. This "concurrent period" provides a major incentive for innovative pharmaceutical companies to begin distributing far more quickly their life-saving medicines in developing countries.

(3) **Eliminate "Linkage" Between Approval of Generics to Certification of Patent Rights:** Previous FTAs have included a requirement that drug regulatory agencies withhold approval of generic drugs until they can certify that there is no existing patent on that product. This not only keeps medicines off the market, it forces drug regulatory agencies to become patent enforcers. The Peru FTA eliminates this requirement. Further, it requires Peru to adjudicate patent disputes quickly – not only claims by innovative drug companies of patent infringement, but also claims by generic producers of patent invalidity.

(4) **Expressly Affirms the Parties' Rights to Take Measures to Protect Public Health:** The Peru FTA affirms the Parties' commitment to the WTO Doha Declaration. The Doha Declaration recognizes the right of WTO members to grant compulsory licenses and to "protect public health … and promote access to medicines for all." The Declaration also creates an explicit exception to data exclusivity rules for "measures to protect public health" and clarifies that the intellectual property provisions of the FTA do not prevent countries from taking measures to protect public health. The Peru FTA thus ensures that compulsory licensing of medicines will always be available as a tool to address public health crises—such as medications for the nearly 100,000 Peruvians living with HIV/AIDS.

These long-sought changes are a core component of the groundbreaking new Democratic trade policy. I urge your support for this pro-public health agreement, which finally strikes a fair balance between promoting access to affordable medicines and protecting pharmaceutical innovation.

Sincerely,

Jim McDermott
Member of Congress